Rec'd PCT/PTO 14 OCT 2004

USE OF THERMOREGULATORY MATERIAL TO IMPROVE EXERCISE PERFORMANCE

FIELD OF THE INVENTION

The present invention relates generally to the use of a thermoregulatory material to improve exercise performance, and more specifically to use of such material to improve exercise performance in the heat by maintenance of core temperature, by increasing exercise tolerance time, and/or by the chemical/phase-change properties of the material.

BACKGROUND OF THE INVENTION

I. Thermoregulation During Exercise, or High Temperature Exposure

The physiological requirements for thermoregulation during exercise or high temperature exposure are considerable and if proper measures are not in place to maintain homeostasis, heat exposure can sometimes lead to death. Body temperature, or specifically core temperature is in constant dynamic equilibrium with factors that can add and subtract heat from the body. This balance is maintained by the integration of mechanisms that alter heat transfer to the periphery, regulate evaporative cooling, and vary the rate of the body's heat production. Quite simply, if heat gain exceeds heat loss, which frequently occurs during vigorous exercise, the core temperature of the body rises.

Specifically, core temperature is in constant dynamic equilibrium with factors that can add and subtract heat from the body. Methods by which the body loses heat energy include radiation, convection, conduction and evaporation. During radiation, the body loses heat in the form of infrared heat rays, or electromagnetic waves that radiate from the skin to any surrounding fluid that is cooler than the skin itself. This loss increases as the temperature of the surroundings decreases. Conduction is the least significant form of heat loss under abnormal conditions, such as touching an object that is cooler then the temperature of the skin's surface. However, heat is actually the kinetic energy of molecular motion, and the molecules that compose the skin of body are continuously undergoing vibratory motion. Thus, the vibratory motion of the skin molecules can cause increased velocity of motion of the air molecules that come into contact with the skin. The signals that arise in peripheral

receptors (that of the skin) are transmitted to the posterior hypothalamus, where they are integrated with the receptor signals from the anterior hypothalamic preoptic area to give the final efferent signals for controlling heat loss and heat production. Therefore, we generally speak of the overall hypothalamic temperature control mechanism as the *hypothalamic thermostat* (Guyton et al, 1997). The temperature of the air immediately adjacent to the skin approaches the temperature of the skin, and an additional exchange of heat from the body to the air is self-limited unless the heated air moves away from the skin so that new, unheated air is continuously brought in contact with the skin, a phenomenon called convection (Guyton et al, 1997).

Evaporation is another means of simply sweating, uncontrollably, the heat from the body, all controlled by the body's own thermostat, the hypothalamus. The equilibrium or core temperature is maintained by the integration of mechanisms that alter heat transfer to the periphery, regulate evaporative cooling, and vary the rate of the body's heat production. If heat gain exceeds or is greater than heat loss, which occurs frequently during intense or heat stressed exercises, the core temperature of the body increases. If dehydration (loss of fluids, extracellular and more critically, intracellular) progresses and plasma volume (concentration of water in blood plasma) continues to decrease, sweat rates decrease or become reduced and thermoregulation becomes progressively more difficult. Outlined in a study by Morimoto et al. (1998), dehydration impairs thermoregulation, reducing both sweating and cutaneous vasodilation, while dehydration-induced hyperosmolality causes a shift of body fluid from ICF to ECF and also stimulates drinking behavior, which counteracts the decrease in blood volume. According to Kerslake (1972), an elevated heart rate during dehydration is attributed to a reduced central blood volume, which leads to a lower ventricular filling pressure, and a 25% to 30% reduction in the heart's stroke volume, while the elevation in core temperature is related to a reduction in both sweating rates and blood flow to the skin. Not only does the body core increase in the heat, but also the correlating reduction in plasma volume could lead to circulatory failure. In addition, maximal cardiac output and VO2max are reduced during exercise in the heat because the reflex compensatory increase in heart rate is insufficient to offset the stroke volume decrease (McArdle et al., 1996). Stroke volume during exercise in different environmental conditions combined with hydration increases due

to an increase in heart rate and a reduced blood volume in both hot and cold environments (González-alonzo et al., 2000).

According to Crandall et al., cardiopulmonary baroreceptor unloading coinciding with passive heating attenuates the elevation in cutaneous vascular conductance. In other words, skin blood flow can be modulated by such baroreceptors. Also, the infusion of saline, a substance that increases cellular osmolarity, was found to increase skin blood flow during passive heating (??1999).

Although there seems to be a lag in the onset of sweating at the beginning of exercise, it has been well documented that sweating (evaporation) provides the major physiologic defense against overheating. Heat is continually being evaporated through the skin into the environment as water. The sweating rate of any given individual is dependent upon the climatic conditions/environmental acclimation, the type of clothing worn, and the level of exercise intensity. (Sawka et al., 1998.) Sawka et al. conclude that persons wearing protective clothing often have sweating rates of 1 to $2 L \cdot h^{-1}$ while performing light intensity exercise. Protective clothing such as the nuclear, biological, and chemical (NBC) ensemble worn by military personnel, the protective equipment worn by football players, or the sauna suit features high insulation and low water vapor permeability, due to the thickness and the multilayered fabric design. This layering effect traps insulative air layers around the body and impairs the transfer of heat to the environment. The limited evaporative heat loss allowed by the protective clothing, combined with an increased metabolic heat production and high ambient temperature, can increase the body's core temperature to dangerously high levels. These conditions define uncompensable heat stress, wherein the evaporative cooling requirements (E_{req}) greatly exceed the maximum evaporative potential (E_{max}), which maintains thermal equilibrium. It is not uncommon, therefore, for conditions that would normally be defined as compensable heat stress, to become uncompensable when protective clothing is worn (McLellan et al., 1999). The heat strain associated with wearing NBC protective clothing has been studied for many different combinations of ambient temperature, vapor pressure, and metabolic rate (Carter and Cammermyer, 1985; Kraning and Gonzalez, 1991; McLellan, 1993; Montain et al., 1994).

II. Plasma Volume During Exercise and/or High Temperature Exposure

Water provides the solvent for biochemical reactions within cells, is the medium for material transport, and is essential for maintaining an adequate blood volume (Sawka and Coyle, 1999). A few hours of intense physical exercise in a hot environment can cause water loss to reach a significant level. This dehydration, both from the intracellular and extracellular compartments, and thus, total body water (TBW) can seriously impede heat dissipation, reduce heat tolerance, and can have even more adverse effects on cardiovascular function and exercise capacity. The effect of exercising in the heat also causes serious decreases in blood plasma volume. Sawka et al. (1996), state that TBW and blood volume have critical influences on human thermoregulation and the performance of exercise in the heat.

Latzka et al. (1997), examined the effects of hyperhydration and glycerol loading in subjects while they performed heat-stressed exercise bouts, and found that both hyperhydration and an increase in glycerol had beneficial effects on thermoregulation, such as increased sweat rates. However, neither hyperhydration nor glycerol loading provided any thermoregulatory advantage over the maintenance of euhydration during compensable heat stress, even after acclimatization took place (Latzka et al, 1997). Further, Armstrong et al. (1997), examined the effects of hypohydration, dehydration, and water intake during exercise in the heat, and found that after an increase in water intake (increased load on plasma volume) resulted in a greater increase in the need to maintain hydration levels at a consistent level with that of initial water intake levels. It was also suggested that changes in plasma osmolarity levels from loading before exercise in the heat, rate of fluid intake combined with core temperatures (CRTP) and skin blood flow (SKFL) may suggest that heavy loads of water intake during exercise may not be beneficial for thermoregulatory effectiveness during such conditions (Armstrong et al., 1997). The authors also observed the same osmotic loading with food intake; concluding that both should be avoided in prolonged exercise bouts in the heat.

During exercise as dehydration progresses thermoregulation becomes progressively more difficult, due to the fact that a large portion of water loss through sweating comes from the blood plasma, the body's circulatory capacity is adversely affected as sweat loss progresses. Sawka et al., (1992), states this is evident by a decrease in plasma volume, a reduced skin blood flow for any given core temperature,

a decrease in stroke volume and heart rate, and a overall decrease in circulatory and thermoregulatory efficiency.

The goal of any rehydration strategy is to maintain plasma volume so that circulation and sweating can progress at optimal levels. The intake of fluid during exercise increases the blood flow to the skin, which allows for more effective cooling. In addition, it is well documented that fluid replacement is an important determinant of exercise tolerance time (TT) (Noakes, 1993). Cheung and McLellan (1998) reported that fluid replacement during uncompensable heat stress resulted in a significantly lower heart rate and longer (TT). Although their findings are consistent, it seems to lack evidence on the importance of hydration status during uncompensable heat stress. A consensus written by Maughan, and Shirreffs, (1998), outlines that dehydration per se, even without concomitant hyperthermia may cause the general responses outlined above. Maughan and Shirreffs concluded, that an individual who is both dehydrated and hyperthermic attempts to maintain an adequate cardiac output by an increase in systematic vascular resistance.

Baroreceptors in general, play an important role in regulation of arterial pressure. When arterioles stretch, baroreceptor are stimulated and send barorages up to the medulla of the brain and in turn send pulses to the heart to slow down its pumping actions. An important study by Crandall et al., (1999), suggested that exposure to heat stress could possibly be related to an unloading of baroreceptors causing a resulting increase in skin blood flow. At this point, little is know as to why the increase in temperature causes this unloading to happen, and the authors of this study conclude that thermoregulatory differences from person to person should be highly considered due to possible acclimatized differences.

III. Thermoregulation in Sports

Sports and exercise are perfect conditions to study the effects of heat-stress caused by the environment. Sports is an area where exercise intensity levels range from very moderate, to extreme conditions. Some sports, such as long distance running or rowing have outcomes that are not only affected by fitness levels of the athletes, but by environmental stresses as well. Such sports as football have gained much attention surrounding the quality of practices and the threatening conditions to which players are exposed. Players can end up wearing equipment that adds upwards of an extra 15lbs. This extra weight from the amount of equipment causes the players

to sweat more as their muscles have to work that much harder to compensate for the additional weight. Although advances have been made in the quality of equipment that is used by such athletes, additional weight still causes an increased stress load on the body. While most of today's equipment is designed to allow proper ventilation, professionals in various sports still have to contend with the increasing stresses placed on the body caused by the environment. Accounts have been filed concerning death related to exhaustion caused by heat-stress in overweight football players. Players are trained mentally to push themselves beyond the point of exhaustion in hot-dry environmental conditions, which in Minnesota Viking Corey Stringer's case ended his life instantly.

Athletes of all sports are equipped with the knowledge or provided the coaching to ensure that proper fluid intake is maintained throughout strenuous bouts of exercise. However, fluid intake is only a small part that has to be played in protecting oneself against thermo-exhaustion. Many studies have been conducted concerning the affects of fluid intake and electrolyte balancing, body positioning relative to strenuous exercise, fatigue factors, pattern changes of heat and humidity, and other tolerance variables. An increase in total body water has been suggested to improve thermoregulation during exercise in the heat above euhydration levels (Latzka, et al., 1998). Many related studies have reported that hyperhydration can reduce thermal strain (Johnson et al., 1996; Kraning, K et al., 1991; Lind, 1973; Nielsen et al. 1979), whereas others have suggested that no such thermoregulatory advantage is evident (Latzka et al., 1998). While this seems to be an ongoing debate whether increased hydration does have an effect on thermoregulation, Latzka et al., notes that other studies conducted show increases in water and glycerol intake significantly increase plasma volume, but have no immediate effect on sweat rate or affect on core temperature in either trained or untrained athletes (1998).

Humidity can also be an important factor during performance in the heat. Cochrane et al., (1999) examined the effect that humidity has on thermoregulation of endurance athletes. It was found that trained endurance subjects, although there was a slight variation in plasma volume and sweat rate, heat load was the greatest factor affecting thermoregulation. Although this study notes humidity as non-threatening to thermoregulation, more research should be conducted on the effects of humidity on

thermoregulation on athletes who wear various forms of equipment that impede sweat rates.

IV. Thermoregulatory Strategies

In sports, athletes have to be able to perform at optimal levels sometimes regardless of environmental conditions. Professional athletes in sports such as football, marathon running, rowing, ball hockey, and field lacrosse are just a few examples where the sport is played outdoors and heat exposure is frequent, and remains a constant concern for all involved with the sports. As mentioned before, equipment, fluid intake, environmental conditions and thermoregulatory properties of each individual all contribute to an increased risk of possible thermo exhaustion. Some studies have been conducted on the effectiveness of thermoregulatory strategies during heat-stress. Previous research has shown findings suggesting useful methods to use in order to help maintain homeostasis in the heat. Cochrane et al., (1999) performed a study on the changing patterns of heat and humidity and the influence on thermoregulation and endurance performance. The authors also investigated which time of day would be best to hold an endurance competition based on environmental stress on the body. They proposed that a warming pattern or temperature change (morning) would allow maintenance of homeostasis better than a cooling pattern or temperature change (afternoon). The study consisted of a two-hour exercise session during which increasing temperature and decreasing relative humidity conditions were compared to an identical exercise session during a pattern of decreasing temperature and increasing relative humidity. Results from this study showed that as the days of testing continued, heart rate decreased and sweat rate increased from 1.08 l/day to 1.18 l/day given similar testing conditions. The authors concluded that mean heat load is more important than patterns of change in temperature and humidity in determining whether homeostasis in the heat can be maintained. Although sweat rate was higher in the cooling conditions during tests than in the warming conditions, homeostasis was achieved and was similar between the cooling and warming conditions.

According to Latzka et al., (1998), dehydration during prolonged exercise in the heat is already known to exacerbate cardiovascular strain, increase core temperature and impair endurance performance compared with when fluids are ingested during exercise. González-Alonzo et al. (1997) examined the amount of

cardiovascular stress produced in several conditions, including the combination of dehydration and hyperthermia during moderately intense exercise in the heat, dehydration alone, and hyperthermia alone. While skin temperature remained similar through out all three conditions, the combined effect of dehydration with hyperthermia showed the greatest reduction in stroke volume, increase in heart rate, and a decline in mean arterial pressure.

During heat acclimatization, athletes will spend upwards of several days in an environment that is similar to that of the following competition. This is nothing new to athletes in sports such as marathon running, or even triathletes. Although acclimatization has been proven to be an effective mechanism against environmental stresses, athletes of some other sports cannot afford the luxury of spending several days to weeks being acclimatized. For these athletes the best self-defense remains fluid intake for exercise bouts in heat stressed conditions. Rivera-Brown et al (1999), examined the effects of beverage composition on the voluntary drinking pattern, body fluid balance, and thermoregulation of heat-acclimatized trained boys exercising intermittently in outdoor conditions. It was found that flavored drinks with 6% carbohydrate and 18 mmol/l NaCl solution resulted in an increase in intake of 32% compared with water in trained heat-acclimatized boys exercising in tropical climate and the flavored carbo-electrolyte drink prevented voluntary dehydration in the boys who exhibited high sweating rates when exercising in a tropical climate. This study clearly shows the importance of electrolyte replacement after strenuous bouts of exercise in heat-stressed environments. The importance of electrolyte replacement in fluid forms (with NaCl), remains the most important factor in overall recovery during thermoregulation after exercise in heat stressed environments. Not only is proper fluid intake important in maintaining homeostasis within the body, other problems that are associated with prolonged exercise in the heat related to the development of fatigue. As athletes in professional sports where environmental conditions become a health factor, it is important to consider whether or not fatigue has any influence on thermoregulation. González-Alonzo et al., (1999) examined such a problem and found literature that supported the hypothesis in which critically high body temperatures could relate to fatigue in untrained athlete during light exercise in a heat-stressed environment. In this particular study, the main finding was that fatigue during exercise in the heat was related to high internal body temperature. As internal

temperature was increased due to different environmental conditions throughout the study, fatigue set in more quickly than in cooler environmental conditions.

The timing of fluid intake can also be a contributing factory effecting thermoregulation. According to González-Alonzo et al., (1999) fluid amounts and replacement times are just one factor that contributes to thermoregulation during heat-stressed exercise. When examining the effects of exercise while in a supine position compared to upright, it was found that supine versus upright exercise attenuated the increase in heart rate, and a reduction in stroke volume and cardiac output. Even though this particular study does shed a new light onto the effectiveness of exercising in various body positions, it still does not eliminate the problems associated with regular exercise or sports participation while in an upright position.

According to Rivera-Brown et al. (1999), heat acclimatization and training may result not only in an enhanced sweating rate, which may improve heat dissipation by evaporation, but also in greater fluid losses. While the pattern of fluid loss and replacement in heat-acclimatized boys who participate in structured programs has not yet been examined, this study clearly shows the basic principles of the mechanisms involved in thermoregulation.

SUMMARY OF THE INVENTION

The use of a thermoregulating composition of mattter, such as DriWater®, to help thermoregulate a subject user is disclosed. In preferred embodiments, the composition can be situated over significant surface area portions of the user's body (such as by garment-like coverage of substantial portions of the user; on the torso, arms, legs, head, etc., for example) or it can be situated at discrete locations (such as by packs or packets of the material at strategic, heat-intensive areas of the user, for example). Additionally, the composition can be delivered by a variety of means (e.g., directly or indirectly, contained within packets made of either breathable or closed cell material, etc.) to provide the thermoregulatory effects, according to preferred embodiments of the present invention. The application of the thermoregulating composition in the present invention, however, is not limited to the above-recited embodiments; it can be situated or applied by numerous methods over all portions of the body to produce the desired effects, as set forth below.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention is illustrated by way of example and not limitation in the figures of the accompanying drawings, in which like references indicate similar elements, and in which:

Figure 1 is a graph illustrating the mean core temperature change during three experimental trials, which were exercise conditions of no application of DRiWATER® thermoregulatory material, partial (2 packet or "half suit") application of DRiWATER® thermoregulatory material, and full (5 packet or "full suit") application of DRiWATER® thermoregulatory material, according to one embodiment of the present invention;

Figure 2 is a graph illustrating the mean hemoglobin concentration produced by subjects during all three trials, according to one embodiment of the present invention;

Figure 3 is a graph illustrating the mean hematocrit concentrations produced by subjects during all three trials, according to one embodiment of the present invention;

Figure 4 is a graph illustrating DRiWATER® thermoregulatory matreial gel mass as a function of drying time at 35°C and 55% humidity, according to one embodiment of the present invention;

Figure 5 is an illustration (picture) of a front view of the DRiWATER® Body Suit, according to one embodiment of the invention;

Figure 6 is an illustration of a DRiWATER® thermoregulatory material packet, according to one embodiment of the present invention;

Figures 7a and 7b are illustrations of a garment for the upper body designed to carry DriWater packets, according to another embodiment of the present invention;

Figure 8 is an illustration of a garment for the lower body designed to carry DriWater packets, according to one embodiment of the present invention;

Figures 9a, 9b and 9c are illustrations of various head-related clothing-type products designed to supply DRiWATER® thermoregulatory material to the user's head, according to embodiments of the present invention;

Figure 10 is a graph illustrating the average core temperature values of the test subjects from pre- through post- exercise conditions, according to an exemplary experiment concerning one embodiment of the present invention; and

Figure 11 is a table illustrating blood test results for pre- and post exercise conditions, according to an exemplary experiment concerning one embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

A system and method for thermoregulation is described. In the following description, for purposes of explanation, numerous specific details are set forth in order to provide a thorough understanding of the present invention. It will be evident, however, to one of ordinary skill in the art, that the present invention may be practiced without these specific details. The description of preferred embodiments is not intended to limit the scope of the invention or the claims issuing therefrom.

The present invention encompasses a wide range of thermoregulation methods or techniques, with the use of a thermoregulating composition of matter (sometimes referred to as "moisturizing agent") or other thermoregulating material to improve exercise performance corresponding to the presently detailed embodiments. In many

of the embodiments set forth below, the thermoregulatory material was comprised of a moisturizing agent known by the trade name DRiWATER®. According to some preferred embodiments, the chemical composition of the DRiWATER® thermoregulatory material contemplated by the present invention comprises (1) a cellulosic compound ranging from about 1% to about 3% by weight having an average molecular weight ranging between about 90,000 and about 700,000 represented by the formula: R--O--COOM, in which "M" is a metal substituted for hydrogen on said carboxyl group of the cellulosic compound and "R" is cellulosic chain; (2) a hydrated metallic salt ranging from about 0.1% to about 0.3% by weight; and, (3) water ranging from about 97% to about 99% by weight. In another embodiment, the thermoregulatory material comprises about 97.85% water, about 2% CMC (carboxymethol cellulose) and about 0.15% Aluminum Sulfate, mixed together to form a gel.

The moisturizing agent plus nutrients, plus surfactant composition, according to other embodiments of the present invention comprises water, cellulose gum, alum, preservatives, nutrients and surfactant. The basic water, cellulose gum and alum formula is disclosed above. The optional preservatives can be selected from sodium benzoate, potassium sorbate, citric acid, sorbic acid, and niposol M sodium, but is not specifically limited to the above. A combination of two preservatives are required, one with basic pH and one with an acid pH to predictably regulate the liquefaction rate. The amount of each preservative can range from 0.01% to 0.04% by weight as a percentage of the weight of the water used. Nutrients can be trace minerals such as iron, zinc, copper, magnesium, cobalt and manganese but not limited to these and nitrogen, phosphoric acids, potassium nitrate, vitamins and combinations of all of the above. Individual or combinations of nutrients can range from 0.007% to 0.01% by weight as a percentage of the weight of the water used. The surfactant can be quixtar's SA 8 water softener, Air Products and Chemicals, Inc.'s Dynol 604, Brewer International's Sil Energy or any other surfactant that will break the surface tension of water. The surfactant can range from 0.0005 to 0.001% by weight as a percentage of the weight of the water used.

As an example, the present invention composition according to the preferred embodiment can comprise 887 grams water, 18.14 grams CMC, 1.36 grams alum, 1.8 grams sodium benzoate, 1.8 grams potassium sorbate, 0.7 milligrams nutrients and 0.5

milligrams release agent. This makes one quart of DRiWATER® gel with nutrients and preservatives added.

The preferred embodiment of the present invention comprises a mixture of;

97.797%	Water
2.0%	Carboxy Methol Cellulose
0.15%	Aluminum Sulfate
0.02%	Sodium Benzoate
0.02%	Potassium Sorbate
0.008%	Phosphoric Acid & Potassium Nitrate
0.001%	Surfactant

In other preferred embodiments, however, the composition percentages have much broader ranges. In general, these embodiments include the above-disclosed ranges of cellulosic compound, hydrated metallic salt, and water; for example, the CMC (carboxymethol cellulose), Aluminum Sulfate and water composition. This basic formula, in a first modification, can also contain the guar gum and/or Chromium Sulfate constituents, as mentioned above. In some preferred embodiments, the cellulosic guar gum may be in the range of about 0.1% to about 10%. Similarly, the Aluminum Chromium Sulfate can be within the range of about 0.1% to about 0.8%.

A second modification can add preservatives or like constituents such as one or more of those selected from the following groups: (1) Sodium Benzoate, Potassium Sorbate, Citric Acid, Ascorbic Acid, Sulphur Dioxide, and/or Phosphoric Acid; (2) Calcium Propionate, Sodium Nitrate, Sodium Salt of Sulfite, bisulfite, Meta bisulfite, Disodium EDTA, BHA, Potassium bisulfate, and/or BHT butylated hydroxytoluene; and/or (3) Ethanol, Sorbitol, and/or Glycerol.

The composition can also include Oxygen (such as liquid Oxygen) and/or water. With respect to the water, it may be tap and/or filtered water, natural spring water, and/or distilled water. Other ingredients, such as odor eliminators, scents, . fragrances, colors and other additives and uses are discussed in Sections III and IV below.

For purposes of this patent application, the relevant thermoregulatory material can also be any material (in solid, liquid, gel or like form) that performs: (1) basic heat regulating effects similar to DRiWATER®, as detailed below, (2) basic heat regulating effects similar to DRiWATER®, as described below, and additional

microbial/chemical/ phase-change benefits similar to DRiWATER®, or (3) just microbial/chemical/phase-change benefits similar to DRiWATER®.

Further detail of various viable permutations of the DRiWATER® thermoregulatory material, and additional information concerning these embodiments, is set forth in one or more of the following patents and patent applications: U.S. Patent Nos. 4,865,640 and 6,138,408, U.S. Application Nos. 09/096,597 filed June 12, 1998 and 09/645,995 filed September 15, 1999, and international patent application Nos. PCT/US00/41176, PCT/US00/41178, and PCT/US/42,444, filed under the Patent Cooperation Treaty (PCT), all of which are incorporated by reference in their entirety. The present invention is not limited to any of the specific embodiments disclosed in these patents and applications, however.

DRiWATER® can be used as a human thermoregulation mechanism, and is particularly effective during intense bouts of exercise in uncompensable heat stress. DRiWATER® is a substance originally developed for the agricultural industry, whereby it has been shown to restore and retain water levels, and maintain a stable environment in plants. Below, an experiment illustrating the subject matter of this invention is first described, followed by a more detailed description of the relevant structure (garments, etc.). In the experiment, seven male subjects performed two (45 min) trials (at 65% of VO_{2max}) on a treadmill, in an environmentally controlled room set at 35°C. The trials were performed both with, and without the presence of DRiWATER® thermoregulating material. DRiWATER® thermoregulating material (490-633 cm^3) was placed in permeable sacs and secured against the skin at five different sites (head, chest, back, and thighs). The subjects were able to perform longer in a heat-stressed environment when DRiWATER® thermoregulating material was used. These results can be explained by DRiWATER's® thermoregulating material's ability to maintain pre exercise core temperatures (CT), while without DRiWATER® thermoregulating material subject's CT's significantly increased (Pre: 36.6°C; Post: 38.0°C). From an exercise performance standpoint the most significant finding was the subjects ability to extended trial times by an average of 6 minutes with the application of DRiWATER® thermoregulating material. Thus, DRiWATER® thermoregulating material application can improve exercise tolerance time in the heat by assisting in thermoregulation.

I. EXPERIMENT

OBJECTIVES

Several studies have been conducted on the effects of heat stresses and thermoregulation; two by Brock University, Department of Physical Education and Kinesiology, concerning the ability of DRiWATER® to cool the body. Brock University of Ontario Canada is the preeminent testing facility of its kind in North America, handling the testing for the Canadian Olympic Team and the Canadian Military as well as many other athletics-oriented organizations.

For an individual who is stabilized at room temperature, the physiological strain caused by heat accumulation can cause work to be stopped at a physiological level. If an arbitrary upper limit of acceptable strain exists, the time taken to reach this level (tolerance time) would depend on the ambient temperature, humidity, and the characteristics of the subject's thermal state at entry (Kerslake, 1972). At moderate rates of heat gain, the skin temperature does not reach unreasonable levels, unlike what is usually noticed in very severe environmental conditions. Exercise tolerance time may also be limited in the heat by metabolic heat production and the hydration state of the individual. This experiment establishes the effectiveness of DRiWATER's® (DW) ability to aid in human thermoregulation and improve physical performance during intense bouts of exercise in the heat.

METHODS

A. Baseline Measurements

After subjects gave institutionally approved written and informed consent, seven male volunteers (age, 22.8 ± 1.2 years; weight, 100.2 kg; height,182.4 cm; VO_{2max}, 46.17 ml/kg/min^{-1}; relative body fat = 14.3) underwent baseline testing which included weight, height and skin-fold measurements to determine relative body fat (%BF) using a seven-site regression equation (Jackson & Pollock, 1978). Each subject's aerobic capacity (VO_2max) was also measured on a treadmill using a modified Bruce protocol.

B. Exercise Trials

Three 45min sub-max (65% VO_2max) exercise trials where performed on the treadmill in an environmentally controlled room set to 35°C both with, and without the DRiWATER thermoregulatory material suit. The DriWATER® thermoregulatory

material was placed in permeable sacs made of a fabric specially treated for this experiment with anti-microbial material to prevent potential breakdown of DRiWATER® thermoregulatory material. The DRiWATER® thermoregulatory material was evenly distributed and spread in each of these sacks which were pressed against the body using rowing spandex suits. The DRiWATER® thermoregulatory material sacks were located at various sites dependant upon trial: a) head and chest in the half loaded suit condition; b) head, chest, back, and both left and right thighs in the fully loaded DRiWATER® thermoregulatory material suit condition. A total of 490 cm^3 of DRiWATER® thermoregulatory material was used in half loaded suit condition, while 633 cm^3 was used in the fully loaded suit condition.

Each subject was instructed to limit any fluid intake four hours prior to all three trials to ensure they entered the laboratory euhydrated and not affect the plasma volume results. Subject's were instructed to complete the 45-min run for each trial or until they reached volitional exhaustion. Recovery time between trials was one week, which provided adequate time for rehydration, and for the subjects to return in similar physical condition.

Both pre and post exercise subject's oral temperature (OT), (using an oral thermometer), blood samples, height (cm), weight (kg), and hydration (bioelectrical impedance) were measured. Each subject was randomly assigned an order to ensure that the effects produced by DRiWATER® thermoregulatory material were not based on testing familiarity.

Subject's rectal and skin temperatures were monitored through out the exercise trials using electrodes, which were placed at the following sites on the body: temple, chest, thigh, and calf. Total exercise time (minutes) was recorded to measure the effect of DRiWATER® thermoregulatory material on exercise tolerance time. Blood hemoglobin was assessed using the cyanmethemoglobin technique and hematocrit were measured in triplicate after microcentrifugation. Percent change of plasma volume (PV) were calculated from Dill & Costill (1974). Data analysis were conducted using SPSS data-analyzing program.

RESULTS

Upon completion of the testing protocols mean core temperatures were determined for all subjects. Results indicated that when DRiWATER® thermoregulatory material was used at all five selected sites, core temperatures (CT)

remained at pre-exercising levels. Tests performed using no DRiWATER thermoregulatory material 102 showed a significant increase in core temperature, as shown in Figure 1. A significant ($p < 0.05$) increase in performance time was also observed while exercising in the heat while using DRiWATER® thermoregulatory material as a thermoregulatory aid (see Table 1, below). Changes in exercise duration are also noted in percentages.

Table 1
Performance times with fully loaded DW suit, half loaded DW suit and suit without DW

	Exercise Time (min) (mean $\pm$ SE)	**Time Difference (min) (mean $\pm$ SE)**
No-DW	29.3 ± 2.8	
Half-DW	34.5 ± 3.6	4.9 ± 0.8*
Full-DW	36.9 ± 3.0	7.1 ± 0.8**

*P<0.05 in comparison with no DW
**P<0.05 in comparison with no DW

With fully loaded DRiWATER® thermoregulatory material suit exercise time was significantly ($p<0.05$) increased by 19.2%. When half loaded DRiWATER® thermoregulatory material suit was worn, the exercise time was 14.2% longer ($p<0.05$) than suit without DriWATER® thermoregulatory material, significantly ($p<0.05$) less than with fully loaded suit. Results displayed significant changes in hemoglobin and hematocrit concentrations (see Figure 2, Mean Hemoglobin Concentrations Produced by Subjects During All Three Trials, and Figure 3, Mean Hematocrit Concentrations Produced by Subjects During All Three Trials). Hemoglobin remained constant throughout the two DRiWATER® thermoregulatory material trials, while it did not fluctuate as significantly when no DRiWATER® thermoregulatory material was applied. However, a significant change in hematocrit was found between pre and post measurements during the DRiWATER® thermoregulatory material trials indicating lower water loss.

DISCUSSION

The unique quality from the perspective of exercise physiology in relation to DRiWATER® thermoregulatory material is its ability to remain "cool" in any environment. When exposed to an open flame, DRiWATER® thermoregulatory material does not react as water does (i.e., boil or evaporate). The ability for DRiWATER® thermoregulatory material to remain "cool" for such an extended period of time at any room temperature (approximately 1.5 hours) is manifest of the composition that provides it its ability to aid in maintaining CT in a hot environment. When applied to the body through permeable sacks, heat transfer occurs from the body to the DRiWATER® thermoregulatory material, making the subject cooler than he or she would be without DRiWATER® thermoregulatory material.

The physical characteristics and properties of DRiWATER® thermoregulatory material contribute to the overall effectiveness of DRiWATER® thermoregulatory material as a thermoregulatory aid under various conditions (both physical and environmental). When used as a thermoregulatory aid, DRiWATER® thermoregulatory material assists in maintaining homeostasis, allowing increased exercise tolerance time in the heat. DRiWATER® has also been established as a thermoregulatory aid that helps reduce the amount of water lost during exercise in the heat (see Additional Experiment, below). Furthermore, plasma volume of users remained closer to pre-exercising levels with the use of DRiWATER® thermoregulatory material during exercise in the heat. Thus, DRiWATER® thermoregulatory material assists in maintaining homeostasis during exercise in the heat.

Indeed, all tests done so far (see immediately below and Section III) show improved plasma concentrations with use of DRiWATER® thermoregulatory material. As in the previous study this contributed to significant increase in performance time for the athletes during the exercise trial in the heat. Also core temperatures remained at pre-exercising conditions, while skin-surfaces temperatures showed no significant changes.

EXPERIMENT DATA

For the initial visit, the subjects reported to the laboratory euhydrated. The subject's Height (cm), Weight (kg), Body Composition, and $VO_{2\,max}$ were measured.

For the trial with no DRiWATER® thermoregulatory material, the subjects reported to the laboratory in similar state of hydration (euhydrated). The subject's Weight (kg), Bioelectric Impedance Analysis (BIA), Hemoglobin, Hematocrit, Plasma Volumes, and Temperature (Rectal, Auditory, Temple, Chest, Back, Thigh, Bicep) were measured during the trial.

For the full DRiWATER® thermoregulatory material trial (Head, Chest, Back and Thighs; added weight 0.74 kg), the subjects reported to the laboratory in a similar state of hydration (euhydrated). Again, their Weight (kg), Bioelectrical Impedance Analysis (BIA), Hemoglobin, Hematocrit, Plasma Volumes, and Temperature (Rectal, Auditory, Temple, Chest, Back, Thigh, Bicep) were measured during the trial.

For the partial DRiWATER® thermoregulatory material trial (head and chest; 0.3 kg), the subject reported to the laboratory in a similar state of hydration (euhydrated). Again, the subjects' Weight (kg), Bioelectrical Impedance Analysis (BIA), Hemoglobin, Hematocrit, Plasma Volumes, and Temperature (Rectal, Auditory, Temple, Chest, Back, Thigh, Bicep) were measured.

The exercise consisted of a treadmill run (65-70% VO_{2max}, Maximum 45 minutes), with environmental condition of 36°C, and 40% relative humidity. Subjects were euhydrated at the beginning of the trials and no rehydration was provided during the trials. Experimental data is summarized on Tables 2 – 5, below.

Table 2 – BASELINE DATA

Initial Pretreatment Subject Characteristics (DEXA Results)

Variable	Subjects (n=7)	Range
Age (years)	22.9 ± 3.0	19-27
Height (cm)	182.9 ± 9.3	170-197
Weight (kg)	92.1 ± 17.7	80-118
Relative Body Fat (%)	14.2 ± 5.1	8.9-22
Aerobic Capacity ($VO_{2\,max}$)	46.3 ± 6.5	37.8-53.8
Resting Core Temperature (°C)	36.7 ± 0.4	36-37

Relative Body Fat determined by Skinfold Measurements;
All values are means ± SD.

Table 3

Blood Analysis Results Before and After Exercise Periods Under three Conditions (Means ± SD)

	Pretesting			Posttesting		
Technique	No DRiWater	Full DRiWater	Partial DRiWater	No DRiWater	Full DRiWater	Partial DRiWater
Plasma Volume (%)	2.17 ± 0.08	2.2 ± 0.19	2.14 ± 0.11			
Hemoglobin (g/100 ml)	17.1 ± 0.32	16.8 ± 0.8	14.2 ± 7.0	17.6 ± 0.39	17.5 ± 0.36	14.8 ± 7.44
Hematocrit (%)	44.9 ± 2.4	44.2 ± 3.0	37.7 ± 18.5	45.8 ± 0.9	45.4 ± 2.9	38.8 ± 19.1¥

Significant changes pre- to postexercise designated in red (p=0.05). Significant changes pre- to postexercise designated in purple (p= 0.001); ¥ = significant differences between conditions (p=0.05)

Table 4

Weight, Core Temperature and Time Results Before and After Exercise Periods Under three Conditions (Means ± SD)

	Pretesting			Posttesting		
Technique	No DRiWater	Full DriWater	Partial DRiWater	No DRiWater	Full DRiWater	Partial DRiWater
Weight (kg)	91.1 ± 17.5	91.8 ± 17.3	98.5 ± 16.5	90.2 ± 17.7¥	90.8 ± 17.0	97.8 ± 16.7¥
Core Temp (°C)	36.9 ± 0.8	36.5 ± 0.4	36.5 ± 0.6	37.6 ± 0.47*	37.3 ± 0.8*	36.8 ± 0.6*
Time (sec)				1811. ± 601.9¥	1994.0 ± 732.1	1927.6 ± 637.5¥

Significant changes pre- to postexercise designated in red (p=0.05). Significant changes pre- to postexercise designated in purple (p=0.001); ¥ = significant differences between No DRiWATER and Partial DRiWATER (p=0.05); Significant Differences between all Conditions*

Table 5
"DriWater Gel"-experiment

Sample	Sample Mass, g	Surface Area, cm^2	Water Flux, g/cm^2 hr at 35°C and 55% Humidity
1	8.6268	9.89	0.034
2	9.2402	9.89	0.035
3	9.6216	9.89	0.036

As seen in Table 4, Core Temperatures increased significantly under No DRiWATER® thermoregulatory material conditions, however, with the application of DRiWATER® Core Temperatures remained at pre-exercise values. Table 5 above shows some physical quantities for the DRiWATER® thermoregulatory material gel such as the Water Flux values that were calculated from the linear portions of Figure 4 (graph of Gel Mass as a Function of Drying Time at 35°C and 55% humidity). Exercise Tolerance Time increased with the application of DRiWATER® thermoregulatory material (subject completed 45 minutes under all conditions); the time extended on average was 5 minutes, 30 seconds for the full suit and 5 minutes, 12 seconds for the partial suit. These findings were consistent with other hot environment hydration studies (Sawka & Coyle; Montain & Coyle, 1992). To summarize the experiment data, DRiWATER® thermoregulatory material has the ability to assist thermoregulation by maintaining both plasma volume and Core Temperature

CONCLUSION

It is evident that the use of DRiWATER® as a thermoregulatory aid when exercising in the heat has significant thermoregulatory benefits. DRiWATER® thermoregulatory material is unique in that is maintains a "cool" temperature for an extended period of time in any heated environment.

II. THERMOREGULATORY SYSTEMS

BODY SUIT

The Body Suit embodiment is a fully integrated temperature controlling athletic garment designed to maintain core body temperatures below normal rates during intensive exercise. The Body Suit was developed after the experiments recited herein, and thus differs from the embodiments that were used in the trials (detailed below). A front view of the Body Suit is shown in Figure 5. As seen in Figure 5, the Body Suit is comprised of a fabric clothing portion 502 that has one or more pouches contained therein or thereon to hold the DRiWATER® thermoregulatory material (either by itself or in pouches). As illustrated, the Body Suit 502 is seen with a front pocket area 504 for holding the DRiWATER® thermoregulatory material. Designed for athletes, firefighters, military and for any individuals undergoing strenuous exercise with protective clothing, the Body Suit by DRiWATER® incorporates the latest technology in material with the state-of-the-art temperature-reducing product, DRiWATER® thermoregulatory material.

The Body Suit by DRiWATER® can be designed with pockets in strategic locations where DRiWATER® Inserts are placed, as illustrated in the figures . The chest, thighs, back and head are all locations of the body where heat is dissipated. DRiWATER® Inserts work to aid the body in maintaining core temperature.

The Body Suit by DRiWATER® can be worn under protective clothing to improve the body's ability to cool itself. Weighing in at from as little as 1 ½ pounds to about 4 ½ pounds (when fully loaded with DRiWATER® Inserts), it adds little weight and takes only minutes to put on.

With regard to how the DRiWATER® thermoregulatory material is applied, it may be applied directly to the skin, it may be applied via pockets, pouches or other means constructed of permeable membranes (e.g., any fabric or other material that provides a desired permeability), or it may be applied via pockets, pouches or other means constructed of impermeable membranes (again, constructed of any suitable fabric or other material). An exemplary pouch of DRiWATER® thermoregulatory material is illustrated in Figure 6. As s in Figure 6, the pouch 602 is shown filled with DRiWATER® thermoregulatory material in its semi-solid or gel state.

Turning now to the embodiments that were used during the Brock University trials, according to this embodiment, slices of DRiWATER® thermoregulatory material approximately ¼ inch thick were placed in permeable pouches made of fabric specially treated for this experiment. The fabric used for the trials was a white polyester woven (plain weave) fabric, finished with antimicrobial and water repellent finish. The air permeability of this fabric is 18.1 ft^3/min, with a weight of 3.6 oz/yd^2. It should be emphasized that this material was merely exemplary, as a very wide variety of fabrics or other materials can be used to give effect to the present invention. The type of fabric or other material in which the thermoregulating material is applied either directly into the fabric pouch in the garment, or indirectly by inserting a pack into the pouch in the garment can vary depending upon the environment, user and circumstances, ranging anywhere from extremely porous to closed cell and having any number of thicknesses, bulks, weights and construction. By way of one example (with regard to the porous embodiments), the porosity can be selected according to the relevant microbial/chemical/phase-change benefits desired by the thermoregulating composition of matter or material used, considering such factors as amount of reaction desired, humidity and other environmental conditions, the specific application, the intended use and user, as well as any other conditions that affect the delivery of the thermoregulatory material.

During the Brock University trials, the pouches were pressed against the body using rowing spandex suits and were located at sites of the body where cooling would render the most benefit, i.e., the head, chest, back and both thighs. The test subjects then exercised vigorously for 45 minutes while blood samples, temperature, weight and hydration were measured.

The garment worn on the upper body of the subjects is illustrated in Figures 7a and 7b. As seen in Figure 7a, the garment is comprised of a long-sleeve fabric shirt 702 that has a front pouch 704 located thereon. The front pouch can be located either on the inside of the shirt, the outside of the shirt or intergrated therein, depending upon the desired uses. The pouch can be constructed of the same material as the shirt, or it may be constructed of different material (such as porous material if it is located on the inside of the shirt and the desired application is having the DRiWATER® thermoregulatory material directly contact the wearer's skin). A back view of the long-sleeve fabric shirt 702 is illustrated in Figure 7b. As a complement to the

previous figure, Figure 7b shows the back of the shirt 702 with a rear pouch located thereon. This pouch can be associated with/within the shirt material in the same manner as the front pouch.

The garment worn on the lower body during the Brock University test is illustrated in Figure 8. Figure 8 shows a pair of fabric pants 802 suitable for holding DRiWATER® thermoregulatory material for application to the thighs of a wearer. The illustrated pants 802 include a right thigh pouch 804 and a left thigh pouch 806. These pouches 804 and 806 can be incorporated onto or into the fabric of the pants 802 in any of the same ways that the pouches contained within the shirt are incorporated therein.

The thermoregulatory material of the present invention can also be used in other various applications to a user's body, some of which are shown in Figures 9a – 9c. As shown in Figure 9a, the thermoregulatory material can be incorporated (in any of the same manners addressed above) into a neck ring 904. The neck ring 904 is designed to encircle the neck of a wearer 902, as seen in the figure, in order to provide the desired cooling and other advantages of the thermoregulatory material to the wearer 902. Similarly, as seen in Figure 9b, the thermoregulatory material can consist of or be incorporated into a skull cap 912 that is designed to fit on top of the head of the wearer 910. As with the above-mentioned embodiments, the thermoregulatory material can be applied directly, or incorporated into material that forms the skull cap.

Finally, as seen in Figure 9c, the thermoregulatory material can also be formed into or be made part of a helmet insert 918 that is designed to be placed inside of any variety of helmet 916 in order to provide the beneficial effects to the individual wearing the helmet 916.

APPLICATIONS OF THE INVENTION

A first market having many application of this invention, athletics, can be divided into two main sub-groups: Professional/Collegiate and Recreational. A second main market, non-civilian applications, can be divided into four sub-groups: firefighters, law enforcement, military and mining/industrial.

Professional and collegiate athletes are constantly putting themselves in moderate to extreme conditions of exercise. The very root of improving physical fitness requires the body to be pushed to higher and higher limits and the consequence

is abnormally high core body temperatures. Those athletes that wear equipment are especially susceptible to heat exhaustion. Sports such as football can require players add upwards of 15 extra pounds of gear. This extra weight causes the players to sweat more as their muscles have to work that much harder to compensate for the additional weight. The increased weight combined with the insulative effect of the equipment creates stress on the body and reduces performance.

Athletes undergo extreme exercise during training and in competition. Those athletes that can train for longer periods of time and more vigorously will improve their performance and have an advantage during competition. Maintaining lower core body temperatures during training allows the athlete to do just that.

Safety is a top priority in both professional and collegiate sports. The very nature of training and competing requires a careful balance with the safety of the individual. DRiWATER is a tool for athletes to improve performance while simultaneously increasing their safety.

Several specific sports where we have identified a need and a demand for body coolant products are football, hockey, bicycle racing, track and field and crew. Others, of course, can also benefit from this invention.

With regard to the recreational athletics, ver the last few decades the population has learned that physical exercise improves health and longevity. More people of all ages have taken up exercise. Although not professionals, many amateur and recreational athletes exercise beyond safe levels. Heat exhaustion may be more problematic for the non-professional athlete because the limits of physical endurance are not as apparent. Weekend warriors tend to overexert themselves and need a counterbalance of cooling to reduce the health risk.

The sports we identified for the professional athlete also applies to the recreational athlete. In addition to those sports there are various other market sectors we can include under this category. They include; hiking, camping, laborers (ie. carpenter, farm worker) spectators at sporting events, etc.

In addition to extreme exercise in hot environments, the non-civilian sector is burdened with very heavy protective clothing that inhibits heat transfer, reduces the body's ability to cool itself, and therefore limits overall performance. Non-civilian performance is determined as much by how long an individual can perform the task at

hand as by the quality of the performance itself. Several minutes can make a big difference while fighting a fire or engaged in combat.

The unique quality from the perspective of exercise physiology in relation to DRiWATER® is its ability to remain "cool" in any environment without refrigeration. Ice or other refrigerated synthetic products such as 'blue ice' have been used to cool the body, however they have at least three problems – they are often too cold and can shock the system, they melt quickly and they must be refrigerated. Although advances have been made in the quality of equipment that is available such as better ventilation and fabrics that wick perspiration from the body, there are no products that we have found that can duplicate DRiWATER® capabilities.

Polymer body coolant products are sold in the recreational market and will be competition for DRiWATER. The basic polymer body coolant product in distribution is a neck wrap. Our research indicates DRiWATER has several advantages over polymers. Polymers are synthetic beads or crystals that need to be hydrated to become effective. It takes between 30 to 45 minutes for this to occur. This eliminates any possibility for polymers to enter markets that require a 'ready-to-go' condition. Even in the recreational market people do not want to wait 30 minutes before they can put on the polymer product. DRiWATER is ready to use when it is needed.

Finally, In colder climates, where staying warm is sometimes the problem, DRiWATER® thermoregulatory material is equally as effective for activities that can cause overheating. For example, shoveling snow, skiing or even just walking with heavy clothing regardless of cold temperatures outside can overheat the body to dangerous levels. The very young and the elderly are the most susceptible age groups to heat related problems, thus the applicable age groups are very broad.

III. ADDITIONAL EXPERIMENT

METHODOLOGY

In this exemplary experiment, DRiWATER® thermoregulatory material was applied via gel packs, like that shown in Figure 6, to the head, chest, biceps, forearms, legs and feet of the test subject, although the invention is in no way limited to these body parts.

A. Subjects

After receiving approval from the Brock University Ethics Committee, four non-heat acclimatized bald men 22-30 years of age volunteered to participate in the study. The subjects were informed of all details relating to the experimental procedures and the associated risks and discomforts. After it was determined that there were no medical contraindications to their participation in the experiment, each subject gave written informed consent before the first day of data collection.

B. Determination of VO_{2max}

Each subject's VO_{2max} was determined during the initial visit on the Astrand bicycle ergometer using open circuit spirometry. After the subjects had a three minute warm-up phase at a self-selected pace, the testing began at a workload of 50 Watts. Every minute the bicycle workload was increased by 50 Watts until reaching 250 Watts whereby the testing protocol increased by 25 Watts until volitional fatigue. Throughout the test the subjects were asked to maintain approximately 90 revolutions per minute (RPM). Subjects were given verbal encouragement throughout the test. VO_{2max} was defined as the highest 30 second O_2 consumption observed during the incremental test. Heart rate (HR) was monitored throughout the incremental test using an Acumen heart rate monitor. The value recorded at the end of the exercise test was considered to be the individual's maximal HR.

C. Experimental Protocol

Testing was done in March at the Brock University Exercise Assessment and Research Center. Subjects were not heat acclimated prior to the experiment, and were required to fast for four hours prior to testing. The order of trials was randomised to eliminate any order effect and bias for the extent of the partial heat acclimation that may have been acquired with the repeated testing. On two mornings (with at least five days rest between) each participant underwent a heat stress test, which consisted of riding the Astrand bicycle ergometer at 70% of their predetermined VO_{2max} in a hot environment (28°C, 30% relative humidity), while wearing a sauna suit. One test had the subjects wearing packs of DRiWATER® thermoregulatory water and the other test involved the use of no DRiWATER® thermoregulatory material. Subjects were asked to exercise for a maximum of 45 minutes or until they could no longer continue. If under any circumstance the subject felt pain, nausea, had an abnormal or high heart rate, or they could not maintain 90 RPM the subject was forced to quit exercising.

RESULTS

As expected, core temperature significantly increased after exercise in the heat. However, when DRiWATER® thermoregulatory material was applied, core temperature remained at pre-exercise levels, as seen in Figure 10. Figure 10 illustrates pre and post exercise vs. core temperature (y-axis, °F) values during both test conditions. The total exercise time was on the average 6 min longer with DRiWATER® thermoregulatory material. Although the sample size was small, this difference was quite notable. One of the subjects was able to exercise 10 extra minutes with DRiWATER® thermoregulatory material, which may be important when performing physical activity in extreme heat.

Blood test results are presented in Figure 11. Hematocrit significantly increased after exercise in the heat regardless the DRiWATER® thermoregulatory material application. However, during the test with DRiWATER® thermoregulatory material, subjects showed significantly higher hematocrit. Consequently, post exercise values were also significantly higher during the DRiWATER® thermoregulatory material test. Hemoglobin concentration has been significantly increased from pre to post exercise only during the without DRiWATER® thermoregulatory material test while it did not change significantly. No significant pre to post exercise changes have been observed in TBW, ICW and ECW, as seen in Fig. 11.

In conclusion of the Additional Experiment, DRiWATER® thermoregulatory material can improve exercise performance in the heat by maintaining core temperature near pre -exercise levels and consequently increase exercise tolerance time.

IV. ADDITIONAL EMBODIMENTS

Further exemplary applications of this invention are embodiments wherein the DRiWATER® thermoregulatory material used in hats, helmets, neck rings, or any other headgear directed to the scalp. Any type of pant or top garment may also incorporate the instant DRiWATER® thermoregulatory material invention into one or more portions thereof. In its various applications, the DRiWATER® thermoregulatory material may be applied to the overall body and/or it can be applied to specific body parts. As mentioned elsewhere, the invention is able to be

incorporated into flak jackets or any other protective equipment. Moreover, any variety of fabrics, plastics and other materials can be used to deliver the DRiWATER® thermoregulatory material with the relevant use and environment dictating the range anywhere from very porous cheese-cloth/mesh to very low permeability materials (e.g., silk, etc.), as well as diverse ranges of permeable, semi-permeable and non-permeable metals, plastics and other made-made materials. Finally, in addition to the innumerable athletics-related embodiments, as touched-on herein, the instant invention can also be used in applications such as for mail carriers, construction workers, and/or any others who must endure long periods of time in unfavorable environments.

Other exemplary additional applications of the present invention include thermoregulation for fire fighters, military personnel, police, SWAT and other law enforcement (see, for example, the body armor with cooling systems at www.body-armor.com and www.paca-vest.com), firefighters, users of chemical or biological equipment (e.g., for warfare), and any other activity that either prevents desired heat exchange or requires the use of auxiliary layers of equipment or apparel. Detail of such applications, as well as additional applications of relevance, are set forth in U.S. Patent Nos. 5,709,089, 5,363,663, 5,484,366, 5,787,505, 5,940,880, 6,017,606, and 6,282,729, all of which are incorporated by reference in disclosing exemplary uses of the present invention, including all further uses/applications described within any of these U.S. Patents, such as uses/applications detailed in the context of the prior art, background or other sections of their patent specifications.

In the foregoing, a system and method has been described for thermoregulation. Although the present invention has been described with reference to specific exemplary embodiments, it will be evident that various modifications and changes may be made to these embodiments without departing from the broader spirit and scope of the invention. Accordingly, the specification and drawings are to be regarded in an illustrative rather than a restrictive sense.